



PATENT  
Attorney Docket 44921-5047-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: **Mark B. Rabin**

Application No. **09/982,835**

Filed: **October 22, 2001**

For: **Mutations in the BRCA1 Gene**

Group Art Unit: **1655**

Examiner: **Not Assigned**

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97(b)**

Pursuant to 37 C.F.R. 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached PTO-1449 forms. This Information Disclosure Statement is being filed, to the best of the undersigned's knowledge, before the mailing date of a first Office Action on the merits for the above-referenced application. Accordingly, Applicant does not believe that a fee is due with the filing of this paper.

The present application is a divisional application of Application 09/697,149 (filed October 27, 2000) which is a continuation application of Application 09/038,946 (filed March 12, 1998) now abandoned. Information Disclosure Statements for Applications 09/697,149 and 09/038,946 were filed on March 7, 2001 and October 7, 1998 respectively. Copies of the PTO-1449 forms filed with these Information Disclosure Statements are attached. The Examiner's attention is respectfully directed to the art of record in these prior applications and thus, no references are being submitted.

Applicant respectfully requests that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute prior art. If the Examiner applies any one of the documents as prior art against any claim in the application, and Applicant determines that the cited document does not constitute prior art under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or

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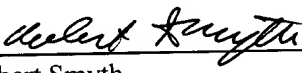
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credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **November 8, 2002**  
Morgan, Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Avenue  
Washington, D.C. 20004  
202-739-3000

Respectfully submitted,  
**Morgan, Lewis & Bockius LLP**

  
\_\_\_\_\_  
Robert Smyth  
Registration No. 50,801



## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

PTO Form 1449

Attorney Docket No.  
44921-5047-01Serial No. **RECEIVED**

09 9828

Applicant: Mark B. RABIN

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Filing Date: October 27, 2000

Group: 1655

## U.S. PATENT DOCUMENTS

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*Examiner Initial	Document Number	Date	Name	Class	Sub Class	Filing Date
	5965377	10/12/99	Adams <i>et al.</i>	435	7.23	
	5593840	01/14/97	Bhatnagar <i>et al.</i>	435	6	
	5582989	12/10/96	Caskey <i>et al.</i>	435	6	
	5547839	08/20/96	Dower <i>et al.</i>	435	6	
	5510270	04/23/96	Fodor <i>et al.</i>	436	518	
	6045997	04/04/00	Futreal <i>et al.</i>	435	6	
	5455934	10/03/95	Holland <i>et al.</i>	395	404	
	5891857	04/06/99	Holt <i>et al.</i>	514	44	
	5221619	06/22/93	Itakura <i>et al.</i>	435	69.4	
	5583013	10/10/96	Itakura <i>et al.</i>	435	69.4	
	6051379	08/18/00	Lescallett <i>et al.</i>	435	6	
	5858669	01/12/99	Levine	435	6	
	4683202	07/28/87	Mullis	435	91	
	6130322	10/10/00	Murphy <i>et al.</i>	536	23.1	
	5912127	06/15/99	Narod <i>et al.</i>	435	6	
	6083698	07/04/00	Olson <i>et al.</i>	435	6	
	5545531	08/13/96	Rava <i>et al.</i>	435	6	

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<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  PTO Form 1449				Attorney Docket No. 44921-5047-01		Serial No. 09 982835	
				Applicant Mark B. RABIN			
				Filing Date October 27, 2000		Group 1655	
<b>U.S. PATENT DOCUMENTS</b>							
*Examiner Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
		5948643	09/07/99	Rubinfeld <i>et al.</i>	435	69.1	
		5693473	12/02/97	Shattuck-Eidens <i>et al.</i>	435	6	
		5709999	01/20/98	Shattuck-Eidens <i>et al.</i>	435	6	
		5589330	12/31/96	Shuber	435	5	
		5726019	03/10/98	Sidransky	435	6	
		5710001	01/20/98	Skolnich <i>et al.</i>	435	6	
		5753441	05/19/98	Skolnick	435	6	
		5747282	05/05/98	Skolnick	435	69.1	
		6124104	09/26/00	Tavtigian <i>et al.</i>	435	7.2	
		6033857	03/07/00	Tavtigian <i>et al.</i>	435	6	
		5756294	05/26/98	White <i>et al.</i>	435	6	
Examiner				Date Considered			
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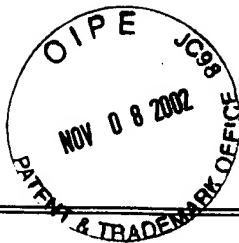
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		Applicant Mark B. RABIN						
		Filing Date October 27, 2000		Group 1655				
<b>U.S. PATENT DOCUMENTS</b>								
<b>FOREIGN PATENT DOCUMENTS</b>								
		Document Number	Date	Country	Class	Sub Class	Translation YES NO	
		WO9730108	08/21/97	WO				
		WO9519369	07/20/95	PCT				
		EP0699754A1	06/03/96	EP				
		W09304200	03/04/93	WO				
		WO9815654	04/16/98	WO				
		EP0705903A1	10/04/96	EP				
		W09722689	06/26/97	WO				
		GB2307477A	05/28/97	GB				
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
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		Applicant Mark B. RABIN	
		Filing Date October 27, 2000	Group 1655
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
		BÉRTWISTLE <i>et al.</i> (1998) Functions of the BRCA1 and BRCA2 genes. <i>Current Opinion Genet. Dev.</i> 8(1):14-20.	
		DUNNING <i>et al.</i> (1997) Common BRCA1 variants and susceptibility to breast and ovarian cancer in the general population. <i>Human Molecular Genetics</i> 6(2):285-289.	
		DURROCHER <i>et al.</i> (1996) Comparison of BRCA1 polymorphisms, rare sequence variants and/or missense mutations in unaffected and breast/ovarian cancer populations. <i>Human Molecular Genetics</i> 5(6): 835-842.	
		HUSAIN <i>et al.</i> (1998) BRCA1 Up-Regulation Is Associated with Repair-mediated Resistance to <i>cis</i> -Diamminedichloroplatinum (II) <sup>1</sup> . <i>Cancer Research</i> 58(6): 1120-1123.	
		JENSEN <i>et al.</i> (1992) Characterization of Baculovirus-Expressed Human $\alpha$ and $\beta$ Platelet-Derived Growth Factor Receptors. <i>Biochemistry</i> 31(44): 10887-10892.	
		JENSEN <i>et al.</i> (1996) BRCA1 is Secreted and Exhibits Properties of a Granin. <i>Nature Genetics</i> 12(3):303-308.	
		MIKI (1994) A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1. <i>Science</i> 266: 66-71.	
		ROWELL <i>et al.</i> (1994) Inherited Predisposition to Breast and Ovarian Cancer. <i>Am. J. Human Genetics</i> 55(5):861-865.	
		RUFFNER <i>et al.</i> (1997) BRCA1 is a Cell Cycle-Regulated Nuclear Phosphoprotein. <i>Proceedings of the National Academy of Sciences (USA)</i> 94(14): 7138-7143.	
		SHARAN <i>et al.</i> Murine BRCA1: Sequence and significance for Human Missense Mutations. <i>Human Molecular Genetics</i> 4(12): 2275-2278.	
		THOMPSON <i>et al.</i> (1995) Decreased Expression of BRCA1 Accelerates Growth and is Often Present During Sporadic Breast Cancer Progression. <i>Nature Genetics</i> 9(4):444-450.	
		VILE <i>et al.</i> (1994) Gene Transfer Technologies for the Gene Therapy of Cancer. <i>GeneTherapy</i> 1(2): 88-98.	
		ZHANG <i>et al</i> (1998) BRCA1, BRCA2, and DNA Damage Response: Collision or Collusion? <i>Cell</i> 92(4): 433-436.	
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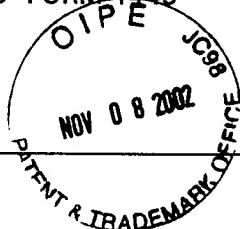
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## LIST OF REFERENCES CITED BY APPLICANT

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PTO FORM 1449



ATTY. DOCKET NO.

09982835

APPLICANT

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FILING DATE

March 12, 1998

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## U.S. PATENT DOCUMENTS

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,458,066	7/3/1984	Caruthers <i>et al.</i>	536	27	
	4,683,202	7/28/1987	Mullis	435	91	
	5,561,058	10/1/1996	Gelfand <i>et al.</i>	435	912	
	5,582,989	12/10/1996	Caskey <i>et al.</i>	435	6	
	5,589,330	12/31/1996	Shuber	435	5	
	5,624,803	4/29/1997	Noonberg <i>et al.</i>	435	6	
	5,633,134	5/27/1997	Shuber	435	6	
	5,650,316	7/22/1997	Aggarwal <i>et al.</i>	435	375	-
	5,654,155	8/5/1997	Murphy <i>et al.</i>	435	6	

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## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	Abeliovich <i>et al.</i> , "The Founder Mutations 185delAG and 5382insC in BRCA1 and 6174delT in BRCA2 Appear in 60% of Ovarian Cancer and 30% of Early-Onset Breast Cancer Patients among Ashkenazi Women," <i>Am. J. Hum. Genet.</i> <u>60</u> :505-514 (1997)
	Antonarakis, S. and McKusick, V., "Discussion on Mutation Nomenclature," <i>Human Mutation</i> <u>4</u> :166 (1994)
	Arteaga, C. and Holt, J., "Tissue-targeted Antisense <i>c-fos</i> Retroviral Vector Inhibits Established Breast Cancer Xenografts in Nude Mice," <i>Cancer Research</i> <u>56</u> :1098-1103 (1996)
	Beaucage, S., and Caruthers, M., "Deoxynucleoside Phosphoramidites - A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," <i>Tetrahedron Letters</i> <u>22</u> (20):1859-1862 (1981)
	Beaudet, A., and Tsui, L., "A Suggested Nomenclature for Designating Mutations," <i>Human Mutation</i> <u>2</u> :245-248 (1993)
	Beutler <i>et al.</i> , "Mutation Nomenclature: Nicknames, Systematic Names, and Unique Identifiers," <i>Human Mutation</i> <u>8</u> :203-206 (1996)
	Cheng <i>et al.</i> , "Microchip-based Devices for Molecular Diagnosis of Genetic Diseases," <i>Molecular Diagnosis</i> <u>1</u> (3):183-200 (1996)
	Conner <i>et al.</i> , "Detection of sickle cell $\beta^S$ -globin allele by hybridization with synthetic oligonucleotides," <i>Proc. Natl. Acad. Sci. USA</i> <u>80</u> :278-282 (1983)
	Cotton, R., "Update on Nomenclature for Human Gene Mutations," <i>Human Mutation</i> <u>8</u> :197-202 (1996)
	Couch <i>et al.</i> , "Mutations and Polymorphisms in the Familial Early-Onset Breast Cancer ( <i>BRCA1</i> ) Gene," <i>Human Mutation</i> <u>8</u> (1):8-18 (1996)
	Easton <i>et al.</i> , "Genetic Linkage Analysis in Familial Breast and Ovarian Cancer: Results from 214 Families," <i>American Journal of Human Genetics</i> <u>52</u> :678-701 (1993)

	Friedman <i>et al.</i> , "Confirmation of BRCA1 by analysis of germline mutations linked to breast and ovarian cancer in ten families," <i>Nat. Genetics</i> <u>8</u> :399-404 (1994)
	Friend <i>et al.</i> , Breast cancer information on the web, <i>Nature Genetics</i> <u>11</u> :238-239 (1995)
	Furner <i>et al.</i> , "Growth suppression of glioma cells by PTEN requires a functional phosphatase catalytic domain," <i>Proceedings of the National Academy of Sciences, U.S.A.</i> <u>94</u> :12479-12484 (1997)
	Hacia <i>et al.</i> , "Detection of heterozygous mutations in <i>BRCA1</i> using high density oligonucleotide arrays and two-colour fluorescence analysis," <i>Nature Genetics</i> <u>14</u> :441-447 (1996)
	Hames, B. and Higgins, S., "Nucleic Acid Hybridization, A Practical Approach," IRL Press, Washington, DC (1985)
	Hogervorst <i>et al.</i> , "Rapid detection of <i>BRCA1</i> mutations by the protein truncation test," <i>Nat. Genet.</i> <u>10</u> (2):208-212 (1995)
	Holt <i>et al.</i> , "Growth retardation and tumour inhibition by <i>BRCA1</i> ," <i>Nature Genetics</i> <u>12</u> (3):298-302 (1996)
	Ikuta <i>et al.</i> , "Dissociation kinetics of 19 base paired oligonucleotide-DNA duplexes containing different single mismatched base pairs," <i>Nucleic Acids Research</i> <u>15</u> (2):797-811 (1987)
	Landgren <i>et al.</i> , "A Ligase-Mediated Gene Detection Technique," <i>Science</i> <u>241</u> :1077-1021 (1988)
	Landgren <i>et al.</i> , "DNA Diagnostics - Molecular Techniques and Automation," <i>Science</i> <u>242</u> :229-237 (1988)
	Maniatis <i>et al.</i> , Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory, NY, pp. 280-281 (1982)
	Merajver & Petty, "Risk Assessment and Presymptomatic Molecular Diagnosis in Hereditary Breast Cancer," <i>Clinics in Lab. Med.</i> <u>16</u> :139-167 (1996)
	Michalowsky <i>et al.</i> , "Combinatorial Probes for Identification of > 100 Known Mutations in Hundreds of Patient Samples Simultaneously Using MASDA (Multiplex Allele-Specific Diagnostic Assay)," <i>American Journal of Human Genetics</i> <u>59</u> (4):A272, poster 1573 (1996)
	PCR. A Practical Approach, IRL Press, Eds. M.J. McPherson, P. Quirke, and G.R. Taylor (1992)
	Saiki <i>et al.</i> , "A Novel Method for the Detection of Polymorphic Restriction Sites by Cleavage of Oligonucleotide Probes: Application to Sickle-Cell Anemia," <i>Bio/Technology</i> <u>3</u> :1008-1012 (1985)
	Sambrook <i>et al.</i> , Molecular Cloning: A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY (1989)
	Sanger <i>et al.</i> , "Cloning in Single-stranded Bacteriophage as an Aid to Rapid DNA Sequencing," <i>J. Mol. Biol.</i> <u>143</u> :161-178 (1980)
	Shattuck-Eidens <i>et al.</i> , "A Collaborative Survey of 80 Mutations in the <i>BRCA1</i> Breast and Ovarian Cancer Susceptibility Gene," <i>JAMA</i> <u>273</u> (7):535-541 (1995)
	Shuldiner <i>et al.</i> , Handbook of Endocrine Research Techniques, pp. 457-486, DePablo, F., Scanes, C., Weintraub, B., eds., Academic Press, Inc. (1993)
	Southern, E., "DNA chips: analysing sequence by hybridization to oligonucleotides on a large scale," <i>Trends In Genetics</i> <u>12</u> (3):110-115 (1996)
	Struewing <i>et al.</i> , "The carrier frequency of the <i>BRCA1</i> 185delAG mutation is approximately 1 percent in Ashkenazi Jewish individuals," <i>Nat. Genetics</i> <u>11</u> :198-200 (1995)
	Tashiro <i>et al.</i> , "Mutations in PTEN Are Frequent in Endometrial Carcinoma But Rare in Other Common Gynecological Malignancies," <i>Cancer Research</i> <u>57</u> :3935-3940 (1997)
	Weber, B., "Genetic Testing for Breast Cancer," <i>Scientific American</i> Jan./Feb.:12-21 (1996)

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